United States Department of Agriculture
Agricultural Marketing Service, Science & Technology
Pesticide Data Program

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Title: Glossary		
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1. Purpose:

To ensure correct and consistent usage of the specific technical terms associated with USDA/AMS-Pesticide Data Program (PDP) Standard Operating Procedures (SOPs).

2. Scope:

This standard operating procedure (SOP) shall be utilized by USDA/AMS and all facilities involved in the collection of samples and performance of analytical determinations for USDA/AMS PDP, including those laboratories which are conducting residue studies for PDP and support laboratories conducting stability or other types of studies that may impact the program.

3. References:

- USDA/AMS PDP Quality Assurance(QA)/Technical Meeting, April 9-11, 2002
- USDA/AMS PDP Quality Assurance Meeting, April 4-5, 2000
- USDA/AMS PDP Quality Assurance Meeting, May 18-20, 1999
- PDP SOP QC-04, revision 2, effective 12/11/92
- U.S. EPA, TSCA Good Laboratory Practices Standard Regulations, 40 CFR part 792
- U.S. EPA, FIFRA Good Laboratory Practices Standard Regulations, 40 CFR part 160
- Taylor, Quality Assurance of Chemical Measurements, 1987

4. Specific Procedures:

4.1. Acronyms and Abbreviations: The following acronyms are sufficiently well known that they may be used in most written documents without further definition:

- AMS (Agricultural Marketing Service)
- CFR (Code of Federal Regulations)
- EPA (U.S. Environmental Protection Agency)
- FDA (U.S. Food and Drug Administration)

- FQPA (Food Quality Protection Act)
- FFDCA (Federal Food, Drug, and Cosmetic Act)
- FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act)
- OSHA (Occupational Safety and Health Administration)
- TSCA (Toxic Substance Control Act)
- USDA (United States Department of Agriculture)

The following should be defined by writing the full name or term and giving the accepted acronym in parentheses immediately following when first used in a written communication and redefined if a significant gap occurs between usages. Those general terms requiring further clarification are defined within the "Glossary of Terms" section of this SOP. Other terms which are specific to a particular SOP may be found within that SOP.

- Atomic Emission Detector (AED)
- Chemical Hygiene Plan (CHP)
- Chemical Ionization (CI)
- Chromatographic Time Segment (CTS)
- Curriculum vitae, plural curricula vitae (CV, CVs)
- Electrolytic Conductivity Detector (ELCD)
- Electron Capture Detector (ECD)
- Electron Ionization (EI)
- Flame Photometric Detector (FPD)
- Gas Chromatograph (GC)
- Good Laboratory Practice (GLP)
- High Performance Liquid Chromatography (HPLC)
- Ion Trap Detector (ITD)
- Laboratory Information Form (LIF)
- Limit of Detection (LOD)
- Limit of Quantitation (LOQ)
- Mass Selective Detector (MSD)
- Material Safety Data Sheets (MSDS)
- Nitrogen Phosphorus Detector (NPD)
- Percent Coefficient of Variation (%CV)
- Pesticide Data Program (PDP)
- Presumptive Tolerance Violation (PTV)

- Quality Assurance (QA)
- Quality Assurance Unit (QAU)
- Relative Retention Time (RRT)
- Remote Data Entry (RDE)
- Retention Time (RT)
- Sample Information Form (SIF)
- Selected Ion Monitoring (SIM)
- Standard Operating Procedures (SOP, plural SOPs)
- Unidentified Analytical Response (UAR)

4.2 Glossary of Terms

1. Administrative Manager: A scientist or other professional of appropriate education, training, and experience, who is designated by participant to administer PDP activities. These activities may include sampling management, laboratory management, budgeting, contracting, purchasing, inventory maintenance, and receipt of QA reports and associated corrective actions.

2. Accuracy: The concept of "exactness" or "correctness". It answers the question, "how close is the result to the true value?"

3. Analytical Method: A procedure consisting of several laboratory procedures, which when completed, produce a quantitative and/or qualitative result for the tested substance.

4. Annual Plan: A general series of projected proposals, actions, and/or activities to be undertaken by an organization during a twelve month period to accomplish its goals and mission.

5. Batch: A specific manufactured or formulated quantity or lot of test, control, or reference substance used in analytical determinations or a study that has been characterized by physical attributes such as a source identity, purity, composition, and stability. Batch can also include a discreet quantity of chemical or product prepared in a single procedure which exhibits uniform characteristics.

6. Below Quantifiable Level (BQL): The amount of residue in a sample matrix that is above the limit of detection and below the limit of quantitation. Confirmed data between LOD and LOQ shall be reported as BQL.

7. Bias: A systematic error inherent in a method or caused by some artifact or idiosyncrasy of the measurement system. Temperature effects and extraction inefficiencies are examples of the first kind. Blanks, contamination, mechanical losses, and calibration errors are examples of the latter kinds. Bias may be both positive and negative, and several kinds can exist concurrently so that net bias is all that can be evaluated, except under special conditions.

8. Calibration: Comparison of a measurement standard or instrument with another standard or instrument to report, or eliminate by adjustment, any variation/deviation in the accuracy of the item being compared.

9. Characteristic: A physical or chemical property that serves to differentiate between compounds. The differentiation may be either quantitative (by variables) or qualitative (by attributes).

10. Check sample: Any matrix sample prepared for the purpose of determining biases, accuracy, and/or precision among analysts and/or laboratories or of a single analyst or laboratory.

11. % Coefficient of Variation (CV): The ratio of the standard deviation, s, of a set of numbers, n, to their average, $\bar{0}$, expressed as a percentage.

$$\% \text{ CV} = (s/\bar{0})*100$$

12. Commodity Grouping: PDP commodity groups established to facilitate method evaluation. Grouping is based on EPA commodity grouping under 40 CFR 180, with modifications to further combine those commodities having similar matrix characteristics for analytical purposes.

13. Confirmation: Verification of an analytical finding.

14. Control Limits: Control chart limits established at the 99% confidence interval for a monitored system. Acceptance limits are set at three times the standard deviation, s, of a system around the best estimate of the data, generally the mean, 0. Thus, control limits established at 0 ″ 3s are expected to contain 99.7% of data produced by a system in statistical control.

15. Data Package: Package containing raw data for an analytical set. Each data package is uniquely labeled by year, month, and commodity and contains, at minimum, the following: instrument methods, reports/summaries of sample results, standardization/calibration reports or summaries, Sample Information Forms (SIFs), Laboratory Information Forms (LIFs), QA Information Forms (QIFs), and documentation of technical and QA review.

16. Data Set: Analytical results transmitted by remote data entry in the same group.

17. Fortification Recovery: The ratio of the measured quantity of a given analyte to the known quantity spiked into the matrix spike. It is usually expressed as a percentage.

18. Homogenate: A sample that has been prepared according to sample preparation instructions and stored under appropriate conditions as stated in USDA/AMS-PDP SOP LABOP-3 paragraph 5.1.

19. Horwitz Expected %CVs: The interlaboratory (between laboratories) and intralaboratory (within laboratory) %CV values predicted by Horwitz based on concentration and defined as:

    Interlaboratory %CV = $2^{(1-0.5\log C)}$, where C=concentration.

    The intralaboratory %CV is defined as b times the interlaboratory value. A table of selected concentrations is presented below:

Concentration (ppm)	**C**	**Expected Interlaboratory %CV**	**Expected Intralaboratory %CV**
1	$1x10^{-6}$	16	11
0.5	$5x10^{-7}$	18	12
0.25	$2.5x10^{-7}$	20	13
0.1	$1.0x10^{-7}$	23	15
0.05	$5.0x10^{-8}$	25	17
0.01	$1.0x10^{-8}$	32	21
0.001	$1.0x10^{-9}$	45	30

20. Intermediate Dilutions: Dilutions from stock solutions used to prepare working solutions.

21. Limit of Detection (LOD): The lowest observable peak response for an analyte above the background noise, 3 times the system noise in matrix. This is normally calculated from a blank matrix in the retention window, or chromatographic time segment (CTS), of the peak of interest. See SOP PDP-QC-10.

22. Limit of Quantitation (LOQ): The lowest concentration for which quantitative analytical data shall be reported in a particular laboratory. This is 3.33 times the LOD or 10:1 signal:noise as described in LOD above.

23. Linearity: May be demonstrated by correlation coefficient where R$0.995/$R^2$$0.990, %RSD ≤ 20%, or % difference of calculated vs. known standard concentration within 15%. See SOP PDP-DATA-03.

24. Marker Pesticides: Analytes specified as required to be spiked for each sample set analyzed due to their characteristics that represent some of the properties of the other analytes screened by that method. See SOP PDP-QC-13.

25. Material Safety Data Sheets (MSDS): OSHA required documentation provided by manufacturers for each chemical produced. Information includes adverse effects, toxicity and other chemical data, and necessary safety precautions.

26. Matrix Blank: Ideally, a previously characterized sample which shows no detectable or defined response for the analyte of interest within that analyte's chromatographic time segment (CTS). If a suitable sample is not available, a portion of one of the samples or purchased (e.g., organic) sample may be used. Refer to QC-01, subsection 5.1.b.

27. Matrix Spike: A blank matrix spiked with a known quantity of analytes. The spike is subjected to the entire analytical method along with samples within that set and provides a measure of the behavior of the analyte(s) for the sample set.

28. Mean: The arithmetic mean of a set of n values is the sum of all values divided by n.

29. Method Evaluation: That study conducted prior to the utilization, distribution, or publication of analytical methodology. The study determines if a specific analysis is feasible and sets acceptable statistical requirements for analytical results for future use of the method.

30. Neat Standard: Solid or liquid form of a pesticide, metabolite, or degradate obtained directly from the manufacturer or distributor with certified purity, expiration date, and lot number.

31. Precision: The degree of mutual agreement among individual measurements under similar experimental conditions.

32. Presumptive Tolerance Violation: A result is considered to be a presumptive tolerance violation if, one, the residue exceeds the tolerance level for a given commodity or, two, the residue found has no established tolerance on the given commodity and is above the limit of detection.

33. Process Control: A compound spiked into each sample in an analytical set to give a measure of the integrity of a particular sample passing through an analytical process. The compound(s) should be chosen as representative of the compounds screened by that method, but should not be a compound of interest.

34. Proficiency Evaluation Sample: A check sample prepared as part of an interlaboratory proficiency testing program to determine accuracy, biases, and/or precision among participating laboratories.

35. Program Administrative Director: A scientist or other professional of appropriate education, training, and experience who is designated by USDA/AMS to be responsible for overall program administrative functions. These functions include program expansion, budgeting, cooperative agreements, memoranda of understanding, and major disbursement of funds.

36. Protocol: Approved written document clearly stating the plan of a study. The protocol shall address, at minimum, the following: objective of the study; sampling, testing, and reporting requirements and procedures; and QA requirements and criteria.

37. Quality Assurance: A system of activities whose purpose is to provide to the producer or user of a product or a service the assurance that it meets defined standards.

38. Quality Control: The overall system of activities whose purpose is to control the quality of a product or service so that it meets the needs of users. The aim is to provide quality that is satisfactory, adequate, dependable, and economical.

39. Quality Control Program: The collection of activities and events that serve to implement a system that assures that the quality of a product, process, or service satisfies the needs of the users.

40. Quality Assurance Unit (QAU): An individual or organizational unit designated by USDA/AMS or the management of an individual testing facility to be responsible for assuring the appropriate management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with USDA/AMS program plans and SOPs. An individual participating facility QAU shall also be responsible for assuring that plans and SOPs issued by the laboratory conform to USDA/AMS requirements and are followed. No QAU duties may be performed by any technical personnel directly involved with the conduct of the analytical findings or a study.

41. Quarterly Plan: A general series of projected proposals, actions, and/or activities to be undertaken by an organization during a three month period to accomplish its goals and mission.

42. Range: The difference between the largest and the smallest value in a set.

43. Raw Data: Any laboratory worksheets, records, memoranda, notes, or exact copies thereof that are the result of original observations and activities of the testing program and are necessary for reconstruction and evaluation of the residue set. Computer printouts, data from automated instruments, chromatograms, maintenance and calibration logs, reference substances and samples etc., could be construed as raw data.

44. Reference Substance: Any chemical substance, mixture, analytical standard, material other than a test substance, or water, that is administered to or used in analyzing the test system in the course of the testing program for the purpose of establishing a basis for comparison with the test substance for known chemical or biological measurements. Most commonly, reference substance refers to an analytical reference standard.

45. Re-injection: Re-injection of initial sample extract with appropriate analytical standards in order to obtain a reportable result(s). Fortification recovery failure, process control failure, instrument malfunction, etc may necessitate re-injection.

46. Relative Percent Difference (RPD): Expression of relative difference between two values. This number is defined as the absolute value between the first result, X_1, and the second result, X_2, divided by the mean of the two results. This is expressed as a percent and calculated as follows:

$$RPD = \frac{*X_1 - X_2*}{[(X_1 + X_2)/2]} \times 100,$$

47. Relative Standard Deviation (RSD): Expression of relative standard deviation of multiple values (e.g., points defining a calibration curve). This number is defined as the standard deviation of the values divided by the mean of the individual response factors. This is expressed as a percent and calculated as follows:

%RSD = [SD / (avg. RF)] x 100,

where SD is standard deviation,

$$SD = \sqrt{\frac{\sum_{i=1}^{n} (RF_i - \overline{RF})^2}{n-1}}$$

and RF is response factor, or the area or height of each standard divided by the concentration of that standard.

48. Remote Data Entry: See SOP PDP-DATA-05.

49. Rerun: Re-extraction of frozen homogenate for analysis. Process control failure, fortification recovery failure, tolerance violation issues, instrument malfunction, etc. may necessitate reruns.

50. Reserve Sample: An aliquot of a homogenate, which is stored under appropriate conditions (see definition of "homogenate" above) for the purpose of replicating tests or when immediate testing cannot be done.

51. Response Factor: Response of an analytical standard expressed as peak area or peak height divided by the concentration of that standard.

52. Review: A formal methodical examination by authorized USDA/AMS personnel of an organization's accounts, financial situation, raw data, records, reports, SOPs, and/or GLP/QA compliance of the laboratory facility, as well as all documents pertaining to the general operation of the facility.

53. Sample: representative portion of material taken from a larger quantity of homogenate for the purpose of examination or analysis which can be used for judging the quality of a larger quantity.

54. Sample Set: A group of samples which are spiked individually with the designated process control(s), extracted on a single day along with the required QC samples, and analyzed with the applicable required QC samples. Each set shall not exceed 24 samples. Required QC samples per set consist of a reagent blank, matrix blank, and matrix spike(s). See SOP PDP-QC-01.

55. Sampling Manager: A professional of appropriate education, training, and experience who is designated by a participant to be responsible for the conduct of the participant's sampling procedures.

56. Semi-Annual Plan: A general series of projected proposals, actions, and/or activities to be undertaken by an organization during a six month period to accomplish its goals and mission.

57. Standard Deviation: Whenever a large number of measurements are made on a particular sample, the results of these measurements are distributed across a curve called a Gaussian Distribution Curve. The standard deviation, s, is a measure of width of distribution, which simplifies the results of a large number of measurements; s represents about 68% of the area, 2s about 95%, and 3s more than 99% of the area on both sides of the curve.

58. Stock Solution: Original solution made from the neat standard in a designated solvent. This solution will be used to prepare further dilutions.

59. Surrogate Spike: See Process Control.

60. Technical Director: A scientist of appropriate education, training, and experience who is designated by USDA/AMS to be responsible for overall sampling and technical conduct of the PDP residue study and monitoring of QA. The conduct includes interpretation, analysis, documentation, and reporting of results in an annual program summary, as well as providing technical guidelines for participating test facilities.

61. Technical Program Manager: A scientist or other professional of appropriate, education, training, and experience, who is designated by a participating laboratory to administer the technical conduct of PDP activities in that facility. These activities may include interpretation, analysis, documentation, and reporting of results.

62. Test Sample: Any item to which the test, control, or reference substance is administered or added to obtain an analytical profile to quantitate test substances or an unknown(s). The test system also includes appropriate groups or components of the system not directly treated with the test, control, or reference substance.

63. Testing Facility: A laboratory involved in the performance of analytical determinations for USDA/AMS-PDP, including those laboratories which are

conducting residue studies for PDP and support laboratories conducting stability or other types of studies which may impact the program.

64. Testing Program: The Pesticide Data Program as conducted by designated sampling and laboratory participants; the program is also referred to as the "study".

65. Test Substance: A chemical substance or mixture of substances administered to or added to a test system as the subject of study.

66. Unidentified Analytical Response (UAR): An analytical response different from that of known reference standards, reagents, and the blank commodity matrix in the sample matrix. The response is generally equal to or more than the response of the process control.

67. Warning Limits: Control chart limits established at the 95% confidence interval for a monitored system. Warning limits are set at two times the standard deviation, s, of a system around the best estimate of the data, generally the mean, 0. Thus, warning limits established at 0 ″2s are expected to contain 95.5% of data produced by a system in statistical control.

68. Working Dilutions: Solutions prepared from neat standards, stock solutions, or intermediate dilutions of stock solutions for spiking or injection.

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- Updated section 3, “References”
- Modified definition for sample set
- Added definitions for linearity, %RSD, and response factor